## UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

United States of America, ex rel. Scott Louderback.

File No. 17-cv-1719 (ECT/LIB)

Plaintiff,

v.

## **OPINION AND ORDER**

Sumitomo Pharma America, Inc., *formerly known as* Sunovion Pharmaceuticals, Inc.,

Defendant.

Jeffrey J. Goulder and Michael Vincent, Stinson LLP, Phoenix, AZ, and Sharon Robin Markowitz, Stinson LLP, Minneapolis, MN, for Relator Scott Louderback.

John P. Bueker and Sandra H. Masselink, Ropes & Gray LLP, Boston, MA, and Joseph T. Dixon, III, and Devin T. Driscoll, Fredrikson & Byron, P.A., Minneapolis, MN, for Defendant Sumitomo Pharma America, Inc., *formerly known as* Sunovion Pharmaceuticals, Inc.

Defendant Sunovion Pharmaceuticals<sup>1</sup> manufactured a drug called Brovana. In this *qui tam* lawsuit brought under the federal False Claims Act, Relator Scott

Louderback claims that Sunovion caused pharmacies to submit fraudulent claims for

Brovana to Medicare.<sup>2</sup> Louderback's fraud theory proceeds in three steps: (1) he alleges

In January 2024, the parties stipulated to amend the case caption because Defendant Sunovion Pharmaceuticals, Inc., had changed its name to Sumitomo Pharma America, Inc. ECF No. 135. Notwithstanding the name change and caption amendment, Defendant in its briefing continued to refer to itself as "Sunovion." *See* Mem. in Supp. [ECF No. 144] at 5 (ECF pagination). That convention will be followed here.

It seems plausible that pharmacies submitted Brovana claims to federal health-care programs in addition to Medicare. The operative Second Amended Complaint mentions only Medicare. *See generally* 2d Am. Compl. [ECF No. 128].

that Sunovion paid rebates to pharmacies in exchange for the pharmacies' agreements to arrange for Medicare patients to receive Brovana prescriptions in situations where the patients would have received a different drug or therapy; (2) this rebates-for-prescriptions arrangement violated the federal Anti-Kickback Statute; and (3) by law, a claim that includes items or services resulting from a violation of the Anti-Kickback Statute in turn violates the False Claims Act.

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Sunovion seeks dismissal of Louderback's Second Amended Complaint. This is the case's second round of Rule 12(b)(6) motions. In the first round, Sunovion's Rule 12(b)(6) motion was granted, and the prior version of Louderback's complaint was dismissed, because the pleading lacked allegations plausibly showing that false claims resulted from Sunovion's assertedly illegal kickbacks. *United States ex rel. Louderback v. Sunovion Pharms., Inc.*, 703 F. Supp. 3d 961, 977–980 (D. Minn. 2023); see United States ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 834–37 (8th Cir. 2022) (interpreting "resulting from" in 18 U.S.C. § 1320a-7b(g) to require but-for causal relationship between kickback and claim). Louderback was given the opportunity to file an amended pleading, and Louderback filed the Second Amended Complaint.

Sunovion's motion will be granted. The Second Amended Complaint alleges facts showing that pharmacies dispensed Brovana and received rebates. It does not take the necessary next step. That is, it does not plausibly allege that the rebates-for-prescriptions agreements caused pharmacies to dispense Brovana in any situation where, absent the agreements, a pharmacy or pharmacies would have dispensed a different drug or therapy.

I

The Second Amended Complaint doesn't change Louderback's core factual allegations. To recap, Sunovion manufactures Brovana, a drug prescribed to treat chronic obstructive pulmonary disease. 2d Am. Compl. ¶¶ 36–37. Considering just pharmacies' acquisition cost and Medicare's reimbursement rate, pharmacies would lose money on Medicare-reimbursed Brovana prescriptions. *Id.* ¶¶ 57–60. Sunovion addressed this problem by paying rebates to pharmacies that signed a "Sunovion Part B Agreement." *Id.* ¶ 68.<sup>3</sup>

Two provisions of the Part B Agreement remain essential to Louderback's claims: what Louderback terms (1) the "dispense-as-written" provision and (2) the "counterdetailing" provision. According to Louderback, these two provisions require pharmacies to dispense Brovana as prescribed by physicians and prohibit pharmacies from educating prescribing physicians regarding less expensive equivalent or generic alternatives to Brovana. *Id.* ¶¶ 76, 79. Based on these Part B Agreement provisions,

The First Amended Complaint attached the Part B Agreement as an exhibit. 1st Am. Compl. [ECF No. 92] ¶ 6 and at 38–49. Though Louderback expressly intended to attach it as an exhibit to the Second Amended Complaint, 2d Am. Compl. ¶ 6, he did not, see generally id. The Part B Agreement will nonetheless be considered in adjudicating Sunovion's Rule 12(b)(6) motion. As a practical matter, Louderback clearly intended to attach the Part B Agreement to the Second Amended Complaint, and it seems safe to presume that its omission was just an oversight. As a legal matter, although it is true that an amended complaint supersedes all previous versions, exhibits attached to previous complaints may be considered if they are necessarily embraced by the operative amended complaint. See Vanderford v. Schnell, No. 22-cv-971 (DSD/DJF), 2023 WL 4489656, at \*1 (D. Minn. July 12, 2023), R. & R. adopted, 2023 WL 4936159 (D. Minn. Aug. 2, 2023). Here, the Part B Agreement is embraced by the Second Amended Complaint because the Part B Agreement remains central to Louderback's claims, it is cited several times, and its authenticity has not been questioned. See Zean v. Fairview Health Servs., 858 F.3d 520, 526 (8th Cir. 2017).

Louderback alleges that Sunovion provides rebates "to pharmacies in exchange for their agreement to arrange for the prescription (by physicians), dispensing (by the pharmacists) and purchase (by patients and pharmacies) of Brovana in circumstances when, but for the [Part B] Agreement, they would prescribe, dispense, or purchase drugs manufactured by Brovana's competitors." *Id.* ¶ 10.<sup>4</sup>

Louderback's Second Amended Complaint adds several paragraphs directed toward causation. *See id.* ¶¶ 122–29. Louderback alleges "[Sunovion] sells Brovana at a wholesale price that exceeds the Medicare Maximum Price." *Id.* ¶ 124(b). "Accordingly, pharmacies cannot profitably offer Brovana to Medicare Part B beneficiaries unless they receive a rebate or discount on Brovana dispensed to those patients." *Id.* ¶ 124(c). The owner of Deines Pharmacy, a pharmacy that signed a Part B Agreement, told Louderback that Deines Pharmacy could not afford to sell Brovana without the Part B Agreement's rebate. *Id.* ¶ 125. The Second Amended Complaint includes eleven example instances where Deines Pharmacy "sought—and received—reimbursement from Medicare Part B while the [Part B] Agreement was in effect." *Id.* ¶¶ 110, 125(b). Louderback alleges

In the first Rule 12(b)(6) round, a theory based on a third "promotional services" provision was dismissed with prejudice. *Louderback*, 703 F. Supp. 3d at 980 n.7. Louderback did not remove allegations regarding this theory from the Second Amended Complaint. *See*, *e.g.*, 2d Am. Compl. ¶¶ 3, 7, 71–72, 89–90, 92–93, 124, 146, 154, 160, and 177. The Second Amended Complaint's restatement of these promotional-services allegations notwithstanding the theory's with-prejudice dismissal prompted Sunovion to file a motion to strike the allegations under Rule 12(f). ECF No. 147. The decision to grant Sunovion's Rule 12(b)(6) motion makes it unnecessary to decide Sunovion's Rule 12(f) motion. The Rule 12(f) motion will be denied as moot.

With the Second Amended Complaint, Louderback filed a declaration of Deines Pharmacy's owner, Mitchell Deines. ECF No. 129. All the statements in this declaration

that "pharmacies failed to substitute Brovana's competitors in situations where, absent the [Part B] Agreement, they would have done so." *Id.* ¶ 126. And "pharmacy sales representatives did not promote Brovana's competitors to physicians in situations where, absent the [Part B] Agreement, they would have done so." *Id.* ¶ 127. Louderback also alleges that these two provisions "protected [Sunovion] from price competition, which resulted in additional sales of Brovana." *Id.* ¶ 128.

II

A

In reviewing a motion to dismiss for failure to state a claim under Rule 12(b)(6), a court must accept a complaint's well-pleaded factual allegations as true and draw all reasonable inferences in the plaintiff's favor. *Gorog v. Best Buy Co.*, 760 F.3d 787, 792 (8th Cir. 2014). Although the factual allegations need not be detailed, they must be sufficient to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). The complaint must "state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[T]he tenet that a court must accept as true all of the

appear in the Second Amended Complaint. For this reason, it is not necessary to consider the declaration, and the declaration does not violate the rule that a party "cannot . . . defend a complaint by relying on a brief or affidavit that describes additional or different allegations that are not in the complaint." *Fuller v. Honeywell Int'l, Inc.*, No. 24-cv-279 (ECT/DJF), 2024 WL 3569496, at \*2 n.4 (D. Minn. July 29, 2024) (citing *Al-Saadoon v. Barr*, 973 F.3d 794, 805 (8th Cir. 2020), and *In re Agape*, 773 F. Supp. 2d 298, 316 (E.D.N.Y. 2011)).

allegations contained in a complaint is inapplicable to legal conclusions." *Id.* These rules are derived from the Supreme Court's interpretation of Rule 8(a). *Twombly*, 550 U.S. at 555; *Iqbal*, 556 U.S. at 680, 684.

In addition to meeting Rule 8(a)'s plausibility requirement, a False Claims Act relator must comply with Rule 9(b)'s particularity-in-pleading requirement. United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006) ("Because the FCA is an anti-fraud statute, complaints alleging violations of the FCA must comply with Rule 9(b)."). "To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." Id. "The claim must identify who, what, where, when, and how." United States ex rel. Costner v. United States, 317 F.3d 883, 888 (8th Cir. 2003). "A relator can meet the Rule 9(b) requirements by pleading (1) 'representative examples of the false claims,' or (2) the 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." United States ex rel. Strubbe v. Crawford Cnty. Mem'l Hosp., 915 F.3d 1158, 1163 (8th Cir. 2019) (quoting United States ex rel. Thayer v. Planned Parenthood of the Heartland, 765 F.3d 914, 918 (8th Cir. 2014)); see also United States ex rel. Benaissa v. Trinity Health, 963 F.3d 733, 739– 40 (8th Cir. 2020).

В

The False Claims Act imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim [to the Government] for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A claim under the False Claims Act generally has three elements: (1) the defendant presented or caused to be presented a claim for payment to the government; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016).

In this case, the alleged falsity arises from claimed violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). 2d Am. Compl. ¶ 27. Specifically, Louderback claims that Sunovion violated § 1320a-7b(b)(2).<sup>6</sup> As relevant here, § 1320b-7b(b)(2) imposes criminal penalties on a person who:

knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[.]

As with the original Complaint, the Second Amended Complaint cites § 1320a-7b(b)(1) as the source of its Anti-Kickback Statute claim. See 2d Am. Compl. ¶¶ 27, 28, 92(b). The Second Amended Complaint's citations to this subsection are an oversight. A § 1320a-7b(b)(1) violation occurs when a person "solicits or receives" illegal remuneration. Here, Louderback claims pharmacies received illegal rebates, but he has not sued them. Louderback targets Sunovion's payment of rebates. A different subsection, § 1320a-7b(b)(2), addresses this conduct. Louderback confirmed at the hearing that the Second Amended Complaint should be understood to rely on § 1320a-7b(b)(2). Tr. [ECF No. 160] at 7, 10.

42 U.S.C. § 1320a-7b(b)(2)(B). "[A] claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g) (emphasis added).

The italicized "resulting from" phrase is critical. When a relator seeks to show that a claim is "false or fraudulent" under the False Claims Act because the claim "includes items or services resulting from a violation of" the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(g), the relator must show a "but-for causal [relationship] between an anti-kickback violation and the 'items or services' included in the claim." Cairns, 42 F.4th at 831. A relator, in other words, must show "that the defendant[] would not have included particular 'items or services' absent the illegal kickbacks." Id. at 835; see United States ex rel. Martin v. Hathaway, 63 F.4th 1043, 1052-53 (6th Cir. 2023) (same); see also United States v. Regeneron Pharm., Inc., Civ. No. 20-11217-FDS, 2023 WL 6296393, at \*7-11 (D. Mass. Sept. 27, 2023) (same). In the context of this case's procedural posture and liability theory, then, Louderback must allege facts plausibly showing that signatory pharmacies would not have included Brovana prescriptions on Medicare claims absent the Part B Agreement's rebates-for-prescriptions arrangement, and he must allege these facts with the particularity Rule 9(b) requires.

C

The Second Amended Complaint's additional causation-directed allegations do not clear Rule 8(a)'s plausibility bar.

(1) Louderback begins by alleging that *just the rebates* Sunovion paid pharmacies that signed on to the Part B Agreement were the but-for cause of Brovana sales because the rebates made it possible for these pharmacies to sell Brovana without losing money. *See* 2d Am. Compl. ¶¶ 124–125. In other words, applying a fundamental economic principle, Louderback points out that no rebates from Sunovion would have meant no Brovana Medicare claims from pharmacies. I understand Louderback to be alleging that every Brovana claim submitted by a signatory pharmacy resulted from the rebates. *See id.* ¶ 125(a)–(c) (explaining that Deines Pharmacy would "never" have sold Brovana without Sunovion's rebates).

This causation theory is not faithful to Louderback's False Claims Act/Anti-Kickback Statute theory. Louderback does not claim that Sunovion's rebates were unlawful merely because they were rebates. He claims the rebates were unlawful because they were conditioned on compliance with the Part B Agreement's "dispense-as-written" and "counterdetailing" provisions.

The Second Amended Complaint's allegations reflect this theory plainly and consistently. *See, e.g., id.* ¶ 3 ("Sunovion paid rebates and provided promotional services to pharmacies and durable medical equipment providers . . . in exchange for their agreement not to promote Brovana's competitors to patients or physicians."); ¶ 10 ("In short, Defendant provides illegal kickbacks to pharmacies in exchange for their agreement to arrange for the prescription (by physicians), dispensing (by the pharmacists) and purchase (by patients and pharmacies) of Brovana in circumstances when, but for the [Part B] Agreement, they would prescribe, dispense, or purchase drugs manufactured by

Brovana's competitors."); ¶ 89 ("In short, the [Part B] Agreement does precisely what the AKS prohibits: Defendant offers participating pharmacies a rebate . . . in exchange for their promise to recommend or arrange for physicians to prescribe, and patients to purchase, Brovana in circumstances in which they would otherwise recommend or arrange for the prescribing or purchasing of another drug."); ¶ 92(a) ("Defendant offered pharmacies a rebate . . . in exchange for their promise to arrange for physicians to prescribe and patients to purchase Brovana in circumstances in which the pharmacies would otherwise recommend one of Brovana's competitors."); ¶ 93(d) ("The [Part B] Agreement gives pharmacies a rebate . . . in exchange for their agreement to suspend their professional judgment and instead act as a salesforce for one particular prescription drug."). If Louderback's theory were that the rebates alone violated the Anti-Kickback Statute, there would have been no need to mention the Part B Agreement's dispense-as-written or counterdetailing provisions in the Second Amended Complaint.

Louderback's motion-to-dismiss briefing confirms that his Anti-Kickback Statute theory depends, not just on the rebates Sunovion paid, but on the Part B Agreement's dispense-as-written and counterdetailing provisions. In his opposition brief, Louderback explained, "rebates are 'discounts' and do not constitute remuneration under the [Anti-Kickback Statute] when they are conditional only on the purchase of a product; but they *do* constitute remuneration if they are conditional on something else (here, the restrictions)." Mem. in Opp'n [ECF No. 152] at 12. Louderback also explained that the "fraudulent scheme . . . is largely contained in the [Part B] Agreement itself—particularly its rebate, no-counterdetailing, and dispense-as-written clauses." *Id.* at 14.

The disconnect between the rebates-only causation argument Louderback advances in opposition to Sunovion's motion and the liability theory he pleads in the Second Amended Complaint is evident in another, seemingly important way. rebates-only causation argument is all-or-nothing. In other words, if Louderback could show but-for causation by identifying just the rebates' economic consequences (that is, the rebates enabled signatory pharmacies to sell Brovana to Medicare beneficiaries at a profit), then the Part B Agreement's rebate provision caused the submission of every Brovana Medicare claim filed by a signatory pharmacy. Louderback appears to confirm this understanding in his opposition brief. See Mem. in Opp'n at 15 ("Thus, all Brovana sales made by pharmacies that entered into the [Part B] Agreement resulted in Brovana Medicare [c]laims."). But the Second Amended Complaint is not all-or-nothing. It does not claim that every Brovana Medicare claim submitted by a signatory pharmacy violated the Anti-Kickback Statute. The pleading is based on the idea that compliance with the dispense-as-written and counterdetailing provisions prompted pharmacies to prescribe Brovana "in situations where they would otherwise have recommended lower priced competitors or generics, such as non-nebulized LABAs." 2d Am. Compl. ¶ 130. Section 1320a-7b(g) and Cairns require Louderback to allege facts plausibly showing that just such "situations" occurred. As I understand Cairns, saying it was "every claim" won't work.

Louderback argues that the Eighth Circuit approves of his rebates-only approach to alleging causation, but this is not persuasive. Specifically, Louderback says "Cairns does not require that all of the activities induced, or sought to be induced, by the kickback

(here, both the pharmacy purchases for resale and the restrictions) cause the Medicare claims, but rather that a violation causes the submission of the claims." Mem. in Opp'n The problem with this contention isn't the take on Cairns; it's that the Anti-Kickback Statute "violation" alleged in the Second Amended Complaint encompasses the rebates in consideration for the dispense-as-written and counterdetailing provisions. In other words, what Louderback must allege to show a "but-for causal [relationship] between an anti-kickback violation and the 'items or services' included in the claim," Cairns, 42 F.4th at 831, depends on the violation alleged. The violation alleged here encompasses more than the rebates. Louderback also cites a series of cases decided by district courts within the Eighth Circuit and says the cases support his causation argument. A careful read of these cases shows they are distinguishable for several reasons, most importantly because none analyzes specifically what a relator must allege to show but-for causation, much more when the alleged Anti-Kickback Statute violation is the payment of rebates conditioned on assertedly unlawful contractual obligations. Mart v. Tactile Sys. Tech., Inc., 595 F. Supp. 3d 788, 808 (D. Minn. 2022); United States ex rel. Grant v. Zorn, No. 4:18-cv-00095-SMR-SBJ, 2021 WL 4145724, at \*8 (S.D. Iowa Mar. 8, 2021); *United States v. Hart*, No. 4:19-cv-00332-JAJ-CFB, 2020 WL 6051599, at \*5 (S.D. Iowa Apr. 1, 2020); Shoemaker v. Cardiovascular Sys., Inc., 300 F. Supp. 3d 1046, 1049 (D. Minn. 2018); United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc., No. 13-cv-3003 (WMW/DTS), 2018 WL 11451362, at \*2 (D. Minn. Oct. 22, 2018).

To remain faithful to his theory, Louderback must allege facts plausibly tracing causation through the Part B Agreement's dispense-as-written and counterdetailing provisions—that is, but for signatory pharmacies' rebates-induced compliance with these provisions, a pharmacy or pharmacies would have dispensed a drug or therapy other than Brovana. Identifying the obvious economic incentives resulting from the rebates alone doesn't carry that pleading burden.

(2) Leaving the rebates-only causation theory aside, the Second Amended Complaint does not allege facts plausibly showing that signatory pharmacies would not have included Brovana prescriptions on Medicare claims absent the rebates-for-prescriptions arrangement reflected in the Part В Agreement's dispense-as-written and counterdetailing provisions.

With respect to this issue, the Second Amended Complaint repeats the basic problem with the pleading's prior version—that is, it alleges causation as a conclusion. The pleading alleges, for example: "Upon information and belief, pharmacies failed to substitute Brovana's competitors in situations where, absent the [Part B] Agreement, they would have done so." 2d Am. Compl. ¶ 126. It also alleges, "upon information and belief, pharmacy sales representatives did not promote Brovana's competitors to physicians in situations where, absent the [Part B] Agreement, they would have done so." Id. ¶ 127. These paragraphs could be characterized as asserting a legal conclusion because they merely frame Cairns's basic rule to fit this case's facts. These paragraphs also could be characterized as conclusory because they allege the ultimate liability-prompting fact without any supporting material. Either way, the allegations do

not plausibly show the but-for causation required under § 1320a-7b(g) and *Cairns*. *See Twombly*, 550 U.S. at 555 (recognizing that Rule 8(a) "requires more than labels or conclusions, and a formulaic recitation of the elements of a cause of action will not do"). Without more, Louderback has not "nudged [his] claims across the line from conceivable to plausible." *Id.* at 570.

It is not difficult to hypothesize facts a relator might allege to plausibly show the but-for causation required under § 1320a-7b(g). For example, the relator might possess personal knowledge of specific situations in which a pharmacist would have dispensed a Brovana alternative but for the Part B Agreement's dispense-as-written and counterdetailing provisions. The relator might possess data showing a significant increase in the number of Brovana prescriptions, and a corresponding reduction in the number of Brovana-alternative prescriptions, beginning with pharmacies' execution of the Part B Agreement. Perhaps the relator might possess scientific studies establishing a causal link between contracts akin to the Part B Agreement and pharmacists' tendencies to adhere to dispense-as-written and counterdetailing provisions. Without these or comparable allegations, the Second Amended Complaint "do[es] not permit the court to infer more than the mere possibility of" causation, but that is not enough to satisfy Rule 8(a) and state a claim for relief. *Iqbal*, 556 U.S. at 679.<sup>7</sup>

The Second Amended Complaint alleges the causal relationship required under § 1320a-7b(g) and *Cairns* "on information and belief." 2d Am. Compl. ¶¶ 126–127. If the allegations in these paragraphs survived Rule 8(a), "assertions based on 'information and belief' are seldom sufficient to satisfy Rule 9(b)." *Hennessey v. Gap, Inc.*, 86 F.4th 823, 831 (8th Cir. 2023). Louderback identifies no reason why this general rule would not apply here.

Louderback argues that the Second Amended Complaint plausibly alleges but-for causation even if his rebates-only causation argument is rejected. See Mem. in Opp'n at 16–19. He says it is reasonable to presume that signatory pharmacies complied with the Part B Agreement's dispense-as-written and counterdetailing provisions and that, had they not complied, pharmacists would on some occasions have prescribed a drug or therapy other than Brovana. See id. I understand § 1320a-7b(g)/Cairns in tandem with Rule 8(a) to require more. In this context, Louderback must allege facts plausibly showing that a pharmacy would not have included Brovana on a Medicare claim but for the rebates-for-prescriptions arrangement reflected in the Part B Agreement. Cairns, 42 F.4th at 836. If presumed adherence to an illegal arrangement were enough, it is difficult to see how § 1320a-7b(g)'s but-for causation element would mean anything at the motion-to-dismiss stage. Regardless, Louderback's arguments are best characterized as allowing an inference of the possibility of causation. That is not enough. *Iqbal*, 556 U.S. at 679.8

Sunovion alternatively argues that actual damages are an element of claim under the False Claims Act and that Louderback has failed to plead them. Mem. in Supp. at 14–15. Because the Second Amended Complaint does not allege but-for causation as required by § 1320a-7b(g), it is not necessary to address this question.

## **ORDER**

Based on the foregoing, and on all the files, records, and proceedings herein, IT IS

ORDERED THAT:

- 1. Defendant's Motion to Dismiss [ECF No. 142] is **GRANTED**.
- 2. The Second Amended Complaint [ECF No. 128] is **DISMISSED with** prejudice.
  - 3. Defendant's Motion to Strike [ECF No. 147] is **DENIED as moot**.

## LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: September 11, 2024 <u>s/ Eric C. Tostrud</u>

Eric C. Tostrud

**United States District Court**